



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3769]

Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions

Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for

Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act." Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the FDA Reauthorization Act of 2017 (FDARA) require that certain presubmissions and submissions for devices be submitted in electronic format specified by FDA beginning on such date as specified in final guidance. It also mandates that FDA issue draft guidance not later than October 1, 2019, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter from the Secretary of Health and Human Services to Congress, FDA committed to developing electronic submission templates and issuing a draft guidance on the topic. This guidance is intended to satisfy the draft guidance documents

referenced in FDA regulations and the MDUFA IV Commitment Letter. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov/>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-3769 for "Providing Regulatory Submissions in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact

information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Providing Regulatory Submissions for Medical Devices in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jacqueline Gertz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1655, Silver Spring, MD 20993, 240-402-9677; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 745A(b) of the FD&C Act (21 U.S.C. 379k-1(b)), amended by section 207 of FDARA (Pub. L. 115-52), requires that presubmissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of the FD&C Act (21 U.S.C. 360(k), 360c(f)(2)(A), 360e(c), 360e(d), 360e(f), 360j(g), 360j(m), or 360bbb-3) or section 351 of the Public Health Service Act (42 U.S.C. 262), and any supplements to such presubmissions or submissions, including appeals of those submissions, be submitted in electronic format specified by FDA, beginning on such date as specified by FDA in final guidance. It also mandates that FDA issue draft guidance not later than October 1, 2019, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. In addition, in the MDUFA IV Commitment Letter¹ from the Secretary of Health and Human Services to Congress, FDA committed to developing "electronic submission

¹<https://www.fda.gov/media/102699/download>.

templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process" and "by FY [fiscal year] 2020, the Agency will issue a draft guidance document on the use of the electronic submission templates." This guidance is intended to satisfy the draft guidance documents referenced in in section 745A(b)(3) of the FD&C Act and the MDUFA IV Commitment Letter.

The Agency has concluded that it is not feasible to describe and implement the electronic format(s) that would apply to all the submissions covered by section 745A(b) of the FD&C Act in one guidance document. Accordingly, this guidance describes how FDA interprets and plans to implement the requirements of section 745A(b)(3) of the FD&C Act, while individual guidances will be developed to specify the formats for specific submissions and corresponding timetables for implementation. Specifically, this guidance discusses: (1) the submission types that must be submitted electronically, (2) criteria for waivers of and exemptions from the submissions in electronic format requirements, and (3) the timetable and process for implementing the requirements.

II. Significance of Guidance

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this document provides such requirements under section 745A(b)(3) of the FD&C Act (i.e., standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See 21 CFR 10.115(d).)

However, this document also contains guidance on additional submission types for which submission in electronic format is not required. To the extent that this guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3), it is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). Such parts of this guidance, when finalized, will represent the Agency's current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used for these recommendations if such an approach satisfies the requirements of the applicable statutes and regulations. This draft guidance contains both binding and nonbinding provisions. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov> or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>. Persons unable to download an electronic copy of "Providing Regulatory Submissions in Electronic Format--Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 19031 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910-0120
814, subparts A through E	Premarket Approval Application	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo Classification Process	0910-0844
"FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act"	513(G) Request For Information	0910-0705
"Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff"	Q-Submissions	0910-0756
800, 801, and 809	Medical Device Labeling Regulations	0910-0485
"Humanitarian Device Exemption Regulation: Q&As"	Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements	0910-0661
"Emergency Use Authorization of Medical Products"	Emergency Use Authorization	0910-0595
601	Biologics License Applications	0910-0338
312	Investigational New Drug Regulations	0910-0014
"Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices"	CLIA Waiver Applications	0910-0598
"Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization"	CLIA Categorizations	0910-0607
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073

Dated: September 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-20949 Filed: 9/25/2019 8:45 am; Publication Date: 9/26/2019]